ACIL LABORATORY ACCREDITATION PERSPECTIVE

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American Council of Independent Laboratories (ACIL)

- Founded in 1937
- Trade association representing independent, commercial scientific and testing laboratories
- Membership is comprised of professional services firms engaged in:
  - ✓ testing
  - ✓ product certification
  - ✓ consulting
  - ✓ research and development
- Affiliate members are manufacturer's laboratories, consultants, and suppliers to the industry

American Council of Independent Laboratories (ACIL)

- **ACIL exists to support the needs of the Independent Testing Industry**

Independent Testing Firms are defined as:

Commercial entities engaged in the following activities for the public:	
Analysis	Product Certification
Testing	Research & Dev
Inspection	Sampling
Materials engineering	Related other consulting services

A N D

Not affiliated with any institution, company, or trade group that might affect their ability to conduct investigations, render reports, or give professional, objective, and unbiased counsel

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ACIL White Paper - 2012

"Economic Benefits of National Environmental Laboratory Accreditation Using an Alternative Accreditation Process"

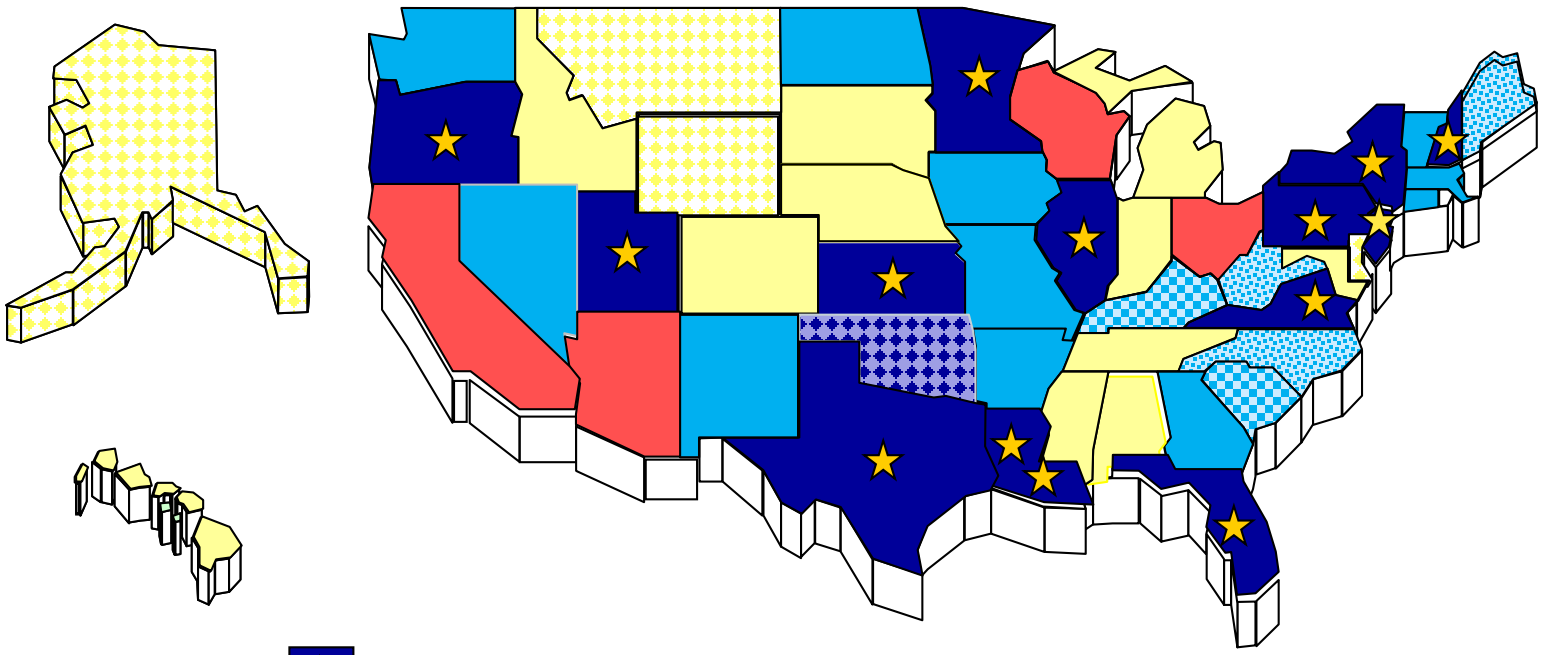
- Summarizes the maturity of the National Environmental Laboratory Accreditation Program (NELAP)
- Outlines the need for the use of 3rd Party Accreditation
- Addresses economic benefit to state budgets
- Outlines the process to migrate from traditional certification/accreditation programs to 3rd party based programs

ACIL Representation

Maxwell Report 2014

- Top 30 Environmental Laboratories
  - ✓ Represent 1.02 Billion in Revenue
- ACIL Environmental Laboratory Members
  - ✓ Represent 9 of the Top 12
  - ✓ Total 672M in Revenue from Maxwell Top 30 members
- ACIL Environmental Laboratory Members represent an estimated 750M of the total available environmental market.

The National Program Today



NELAP Accreditation Body (14)

Accept NELAP (Full reciprocity)

Working on NELAP Application

Accept NELAP & Applies State Reqs

Has a State program that incorporates NELAP elements

State program with significant differences (4)

Drinking Water Primacy Only (12)

Drinking Water Primacy + Specialty Area (ie: UST)

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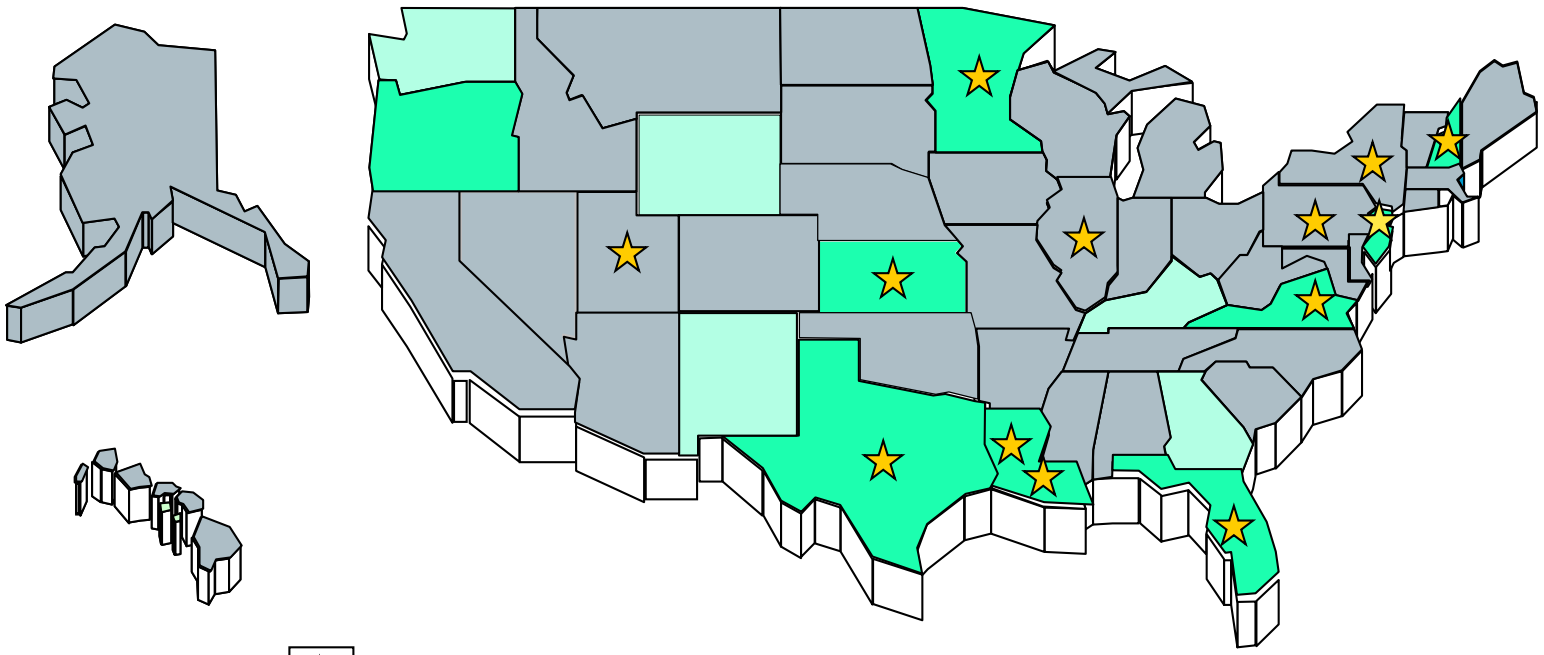
Contract Assessors and 3rd Party Accreditation



NELAP Accreditation Body

States using contract assessors

States accepting 3rd Party Accreditation (General and/or Specialty)

Others using or specifying 3rd Party Accreditation and/or Assessment:

Dept. of Defense, Dept. of Energy, EPA NLLAP, EPA NVLAP, etc.

ACIL Vision for CA ELAP

1. Realization of Equivalency Among Data Producers

- **All labs**, public and private:
  - ✓ Produce data that determines public health and safety
  - ✓ Must be held to the same standard
  - ✓ Perform compliance testing that is key to the future of environmental sustainability and human health
- **No** defendable **reason** for ELAP to have two programs
- Data defensibility is necessary for all compliance monitoring and is not proportional to size
  - ✓ No different than other professionals: Note that the medical profession does not offer different levels of MD's based on population served.
- Size and revenue are not proportional to quality expectation
  - ✓ **All** laboratories are capable of the same level of quality system and technical ability
  - ✓ Environmental equity and justice, knows no budget or size

ACIL Vision for CA ELAP

2. Accreditation Consistency – National Consensus Based Standard

- Adopt a National Consensus Based Standard (TNI Standard)
- CA rejoin NELAP
  - ✓ CA can actively participate in the development , implementation and adoption of the standard.
  - ✓ Provides peer collaboration and support via the Accreditation Council
- Reform current regulations to adopt a **single program** built on a national consensus based standard
  - ✓ TNI is accredited by ANSI and the TNI Standard incorporates multiple ISO standards
- TNI Standard (ISO 17025 Based)
  - ✓ Requires the same foundational quality system regardless of lab type or size.
  - ✓ Defensibility is achieved via adherence to the same requirements for quality, technical, personnel, ethics/data integrity, and documentation
- **Ultimate goal** is to provide data of known and documented quality that is consistent across **ALL** providers, public and private.

WHY the TNI Standard…

- ANSI Accredited
- Incorporates ISO 17025 as the foundation for quality systems
- Most experienced and expansive "brain trust" of individuals participate in the development:
  - ✓ Many more participants and resources than any single agency has
  - ✓ Known experts with specific disciplines, from public & private sectors, including multiple non-NELAP states, collaborate together
- Polices & Processes in place for: Organization, standard development, balance, stakeholder representation, acceptance, and implementation
- Formal Standard Interpretation Request (SIR) Process:
  - ✓ Aids in ensuring consistent interpretation and implementation of the standard
  - ✓ AC must agree on interpretation
  - ✓ Interpretations are incorporated into future standard revisions
  - ✓ Available to entire membership and community
- Requires consistency for method validation, addition of non-traditional analytes, data integrity, data qualification and many other processes not addressed by every individual state program.

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3. Accreditation Consistency – Accreditor Options

- Require program conformance to ISO 17011
- Accept 3rd party accreditation via existing Accreditation Bodies (AB) conforming to ISO 17011
- **All ABs need oversight** to maintain consistency and guarantee improvement
- ABs with no oversight **cannot objectively** identify, monitor and correct their own insufficiencies
  - ✓ TNI ELSS Volume 2 requires a review of each Accreditation Body to ensure uniform conformance to the standard and assess documentation, procedures, qualifications and training
- Utilize TNI's Non Governmental Accreditation Body (NGAB) program to be implemented this year (2015)
  - ✓ TNI ELSS Volume 2 adds value above and beyond pure 17011
  - ✓ The program ensures that all NGABs comply with the TNI Standard
- Utilize known and qualified contract assessors to augment the program (like Florida). This provides access to additional qualified personnel in high volume or unusually busy time periods.
- Laboratories want the **option to choose** a suitable and equivalent path for their needs:
  - ✓ For accreditation
  - ✓ That best fits their needs and requirements for laboratory conformity assessment

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4. Establish Recognition/Reciprocity with Other Programs ….. (states, national entities or private accreditation services)

- Existing programs, currently conforming to the TNI Standard, are **consistently** implemented, enforced, and assessed.

- Existing Reciprocities/recognitions:
  - ✓ 14 NELAP AB's – Full bi-directional recognition
  - ✓ WA – Full recognition of NELAP and A2LA
  - ✓ GA - Full recognition of NELAP and A2LA, ACLASS, AIHA, CALA, NSF, QAI
  - ✓ 29 Others – Full recognition of NELAP
  - ✓ 9 "DW Only" Primacy states will accept NELAP in lieu of home state

NOTE:

- 45 States reference NELAP, in full or part, in their regulations
- DOD incorporates NELAP combined with additional program specific requirements. Accreditation is granted by approved 3rd party accreditors conforming to ISO 17011.

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5. Personnel Consistency

- **Professionalism** and technical knowledge are requirements.
- Adopt personnel requirements that include **training** that is **consistent** with requirements of ANSI, TNI and/or other relevant consensus organizations
- TNI Environmental Laboratory Sector Standard (ELSS) provides qualification requirements for:
  - ✓ Accreditors and Assessors (TNI ELSS V2M1 & V2M3)
  - ✓ Laboratory Personnel (TNI EL V1M2)
- Utilize the available national resources via TNI Educational and Training network
- National standard compliance reaches beyond the program constraints and limited program implementation of the EPA DW Certification Manual (which is insufficient for NPDES, RCRA, and other regulatory programs).

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6. Personnel Qualifications

- Assessors must have:
  - ✓ Actual experience in a testing laboratory
  - ✓ Education in a scientific discipline
  - ✓ The knowledge, experience, and personality to mentor and suggest improvements
  - ✓ Successful auditing experience
  - ✓ Necessary resources to provide assistance
  - ✓ Solid understanding of applicable standards, methods, quality and technology
  - ✓ Desire to stay current on new technology and methods in order to ensure proper implementation and documentation
  - ✓ Credentials that prove their expertise

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7. Fees

- Offer Separate licensing and accreditation options
- Fees should be commensurate with type of accreditation:
  - ✓ Licensing (reduced cost) – "Full reciprocity = less resources"
    - ☆ ELAP labor is limited to review of reciprocal accreditation documents
    - ☆ PT review, Corrective Actions, etc. are the responsibility of the reciprocal/accepted accreditor
  - ✓ Full accreditation via ELAP – ELAP provides all services for accreditation, which requires increased resources thus a higher cost
- Should use above suggested options to:
  - ✓ Save taxpayer monies
  - ✓ Ensure consistency of requirements across CA and neighboring state borders
  - ✓ Move the program to a position of relevance to today's labs and data users

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7. Fees - Example

In 2012 CA NELAP fees were a multiple of ELAP fees:

A fully accredited reciprocal out-of-state commercial lab

NELAP = $17,200 vs ELAP $5400

Both are reciprocal recognitions and are **document review only**, since the primary accreditor is responsible for accreditation details and documents

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8. Proficiency Testing Program

- **Ensure evaluation consistency:** Mandate the use of ISO* approved providers participating in the national consensus based standards process.
- **Provide real time review of PT results**: Require true corrective action, suspension or other actions where necessary.
- **Develop a thorough process for PT review:** Define actions related to unacceptable PTs and enforce in a timely manner
- **Reciprocal/recognized accreditors maintain PT tracking** for their laboratories. No need to duplicate effort.
  - ✓ reduce cost and save time/labor for CA
- **Consider contracting PT review to a 3rd Party –** Save time, resources, and improve accuracy and efficiency

** ISO Guide 34:2009(E) General requirements for the competence of reference material producers.*
ISO 17043:2010(E) General requirements for proficiency testing

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9. Provide Program Services to Labs and Data Users

- Create metrics that reflect accountability measures for timeliness and service. Be transparent regarding operations.
- Keep community updated and provide assistance for regulatory rule changes (fed and state): i.e. Method Update Rule (MUR)
- Provide valuable services and communication in a timely manner to the accredited community
- Provide outreach, quality assurance functions, and assistance to improve the laboratory community
- Provide access to knowledgeable personnel who are available to assist with questions or issues and can provide consistent feedback
- Include up to date program news and FAQs on the ELAP website
- ELAP should help data users (public/private) understand the basic requirements needed to produce data of known and documented quality

Top Priorities

1. Mandate a national consensus based standard (i.e. TNI)
2. Apply the standard to all laboratories
3. Utilize 3rd party resources to remove the current backlog and close gap between current programs and national standard
   a) ISO 17011 Accreditation Bodies (NELAP ABs, NGABs)
   b) Contract assessors
4. Reorganize the program and personnel to support the implementation and maintenance of the national standard
5. Allow for a licensing or full accreditation option with appropriate fees for each
6. Current draft regulations introduce language and acronyms outside of industry standard. Recommend re-writing and simplifying the regulations to reference a national standard and provide support operations accordingly

Conclusions

- All environmental labs produce data that determines current and future public health and safety
- **All labs**, public and private, must be held to the same standard across the entire industry. Labs want a level playing field.
- Complete data defensibility is necessary and is not proportional to laboratory size
- CA needs a single program built on a national consensus based standard (ie: TNI standard) and should rejoin NELAP
- All accreditations should be performed by ABs conforming to ISO 17011
- Labs want a choice for accreditation.
- Options should exist for accreditation and fees:
  - ✓ NELAP – Full service via state or contract assessment, where state evaluates and monitors all requirements, including PTs, Corrective Actions, etc.
  - ✓ NGAB – Licensing by CA via ISO 17011 AB, where accreditor evaluates and monitors all requirements, including PTs, Corrective Actions, etc.

Conclusions

- Establish reciprocity or recognition with other programs conforming to a national consensus based standard
- Adopt personnel requirements that are consistent with requirements of ANSI, TNI and/or other relevant consensus organizations
- Require personnel to be experienced and credentialed
- Mandate the use of ISO accredited providers for Proficiency Testing
- Provide timely, value added, services to the lab community that will promote improvement and consistency while advancing the knowledge base of the laboratory

Thank you for your time!

Questions?

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